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1103326-0525 Div 2


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Berg, et al.
Serial No. : 10/714,577
Filed : November 13, 2003
Examiner : R. Desai
Group Art Unit : 1625
For : SUBSTITUTED CHROMAN DERIVATIVES

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Confirmation No.: 1754

Date of Notice of Allowance: January 12, 2006

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I hereby certify that this paper is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below at the facsimile number <u>571-273-0684</u> .	
Richard J. Sterner	35,372
Agent Name	PTO Reg. No.
	March 22, 2006
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Attn: R. Desai
Art Unit: 1625
Facsimile No.: 571-273-0684
No. of pages: 8

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

LETTER ACCOMPANYING TERMINAL DISCLAIMER

Sir:

This communication is being submitted in the wake of the
January 24, 2006 telephone discussion between the Examiner and

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the undersigned and several subsequent discussions and other exchanges between the Examiner's Supervisor and the undersigned.

This application has been allowed. On December 22, 2005 and again on January 4, 2006, prior to allowance, the Examiner called to discuss actions that Applicants could take that would lead to allowance of the application; these actions included certain amendments to the claims and the filing of a Terminal Disclaimer. During these discussions and a further one, on January 9th, Applicants agreed, through the undersigned, to the claim amendments requested by the Examiner.

However, the undersigned maintained Applicants' stance that the requirement for the filing of a Terminal Disclaimer was unwarranted. The Examiner indicated that she understood the arguments presented during the discussions, and also the ones presented in Applicants' September 22, 2005 Amendment and Response, and that she would present them to her Supervisor. From the issuance of the Notice of Allowance and Notice of Allowability on January 12, 2006, it was the understanding of Applicants and the undersigned that the oral and written arguments were found persuasive and that acknowledgment for the record had been made that the compounds of the instant claims do not constitute obviousness-type double patenting over the compounds recited in the claims of coassigned U.S. Patent No. 6,387,899.

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However, in the January 24, 2006 discussion, following a further call from the Examiner on January 23rd, the Examiner advised that, upon further consideration by her Supervisor and despite the issuance of the Notice of Allowance, a Terminal Disclaimer would have to be filed to effect issuance of a patent from the instant application. In effect, the rejection of the instant claims directed to end products as constituting obviousness-type double patenting over the claims of U.S. Patent No. 6,387,899 was being reinstated by the Supervisory Examiner, after the rejection had been withdrawn and the application formally allowed.

A number of exchanges ensued between the Examiner's SPE, Examiner Tsang, and the undersigned. In the final exchanges, on March 20, 2006, Examiner Tsang indicated that, after her consultation with a "Reviewer," the requirement for a Terminal Disclaimer would stand.

In the interest of avoiding any further delay in processing of this application to allowance, and for that reason alone, Applicants are providing herewith a Terminal Disclaimer over the '899 patent. At the same time, they wish to go on record as emphatically disagreeing with the contention that requirement of such action is warranted.

The compounds of the '899 patent are ones in which the benzo portion of the benzopyran (chroman) structure must be

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substituted by substituent R_9 . R_9 is defined in the claims as " C_1 - C_6 alkyl, C_3 - C_6 cycloalkyl, OCF_3 , $OCHF_2$, OCH_2F , halogen, $CONR_6R_7$, CN , CF_3 , OH , C_1 - C_6 alkoxy, NR_6R_7 , SO_3CH_3 , SO_3CF_3 , $SO_2NR_6R_7$, an unsubstituted or substituted heterocyclic or heteroaromatic ring containing one or two heteroatoms selected from N and O, wherein the substituent(s) is(are) C_1 - C_6 alkyl, or COR_8 ; wherein R_6 , R_7 and R_8 are as defined above..." On the other hand, there is no R_9 , or any corresponding substituent, whatsoever on the benzo portion of the benzopyran structure in the generic formula of present claim 1.

What the Examiners, or at least the Supervisory Examiner and Reviewer, apparently believe is that removal of substituent R_9 from the compounds of the '899 patent to render the instantly claimed compounds constitutes an obvious modification. However, there is no basis in case law or in factual analysis for such an assessment. The Examiners cannot make a valid case that one of skill in the art would be motivated to derive the present compounds from the '899 compounds based on expectation that the former would have the properties of the latter. The presumption is that if a distinct (non-hydrogen) substituent exists on a core structure, it has a bearing on the activity of the compound. If one removes such a substituent altogether and finds that the resultant compound has similar properties to the substituted compound, this would be considered unexpected.

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That a patentable distinction exists between compounds containing the R₉ substituent of the '899 patent and the unsubstituted compounds of the present application is further supported not only by the issuance of the Notice of Allowability (and the statement therein that the double patenting rejection over the '899 patent had been withdrawn "since the patent compounds have the R₉ and there is no motivation to modify it"), but by the Examiner's assessment in the June 22, 2005 Office Action. On page 6 of that Action, the Examiner expressly withdrew the obviousness-type double patenting rejection of instant claim 30 over the claims of U.S. Patent No. 6,384,225, because "the patent compounds teach the compounds with the R₉ on its ring."

The claims of the '225 patent are directed to intermediates in the synthesis of the end products claimed in the '899 patent. Instant claim 30 is directed to intermediates in the synthesis of the instantly claimed end products. The relationship between the instant intermediates and the intermediates of the '225 patent is exactly the same as the relationship between the instant end products and the end products of the '899 patent; the '225 intermediates must have the R₉ substituent, while the present intermediates cannot have it. In other words, the issue in both analyses is whether or not compounds lacking the R₉ substituent are patentably distinct over ones which do have the

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R₉ substituent. Since it has been determined on the record that the instant intermediates, which lead to the instant end products, are patentably distinct over the intermediates which lead to the end products of the '899 patent, there is no justification for deeming the end products of the instant application obvious over the end products of the '899 patent.

A further distinction between the present compounds and the '899 compounds should also be noted. The piperidine and piperazine substituents are fixed at the 5-position of the benzopyran structure of the '899 compounds, whereas the piperidine and piperazine substituents of the present compounds may be attached at any one of the four possible positions on the benzo portion of the benzopyran structure.

The Commissioner is hereby authorized to charge the \$130 fee required under 37 CFR \$1.20(d) for the filing of a Terminal Disclaimer to Deposit Account No. 23-1703. Any other fee(s) which may be due for any reason may likewise be charged.

Dated: March 22, 2006

Respectfully submitted



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Enclosure